ABSTRACT

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Title of diploma thesis : **Development of the Stavility Indicating Method for the Selecled Preparation IV.**

A simple, selective, sensitive and robust method was developed and validated for analysis of unknown impurity of dexamethasone using high performance liquid chromatography. Separation of impurity from dexamethasone and betamethasone was achiewed on Lichrospher 100 RP-18 (250 × 4 nm, 5 µm) column using gradient elution and UV detection on 238 nm. A mobile phase system consisted of (A) water:acetonitrile (75:25) and (B) acetonitrile:TEA 30mmol/l (75:25), pH was adjusted to 7.0 with phosphoric acid. A temperature of column was 30°C, an injection volume was 50 µl and a flow-rate was set up at 2 ml/min. The method showed adequate repeatability with relative standard deviation 3,32 %. The other parameters of validation are reported – linearity (r>0,995), recovery 94,25 %, limit of detection (17 ng/ml) and limit of quantification (56 ng/ml).